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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,777	11/26/2003	Bruce Kevin Wagoner	4237-101	9677

23448 7590 07/05/2007  
INTELLECTUAL PROPERTY / TECHNOLOGY LAW  
PO BOX 14329  
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
07/05/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/723,777	<b>Applicant(s)</b> WAGONER, BRUCE KEVIN	
	<b>Examiner</b> Patricia Leith	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 4/4/07.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-6 and 8-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-6 and 8-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 2-6 and 8-48 are pending in the application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

The previous rejection made under 35 USC 102 (b) over Flick (2001) as well as the rejection made under 35 USC 103(a) over Flick (1989) have been removed due to Applicant's convincing arguments.

### ***Claim Rejections - 35 USC § 103***

Claims 2-6 and 8-16 and 20 -48 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Huard et al. (US 6,485,733 B1) in view of Nagel (1977) in view of Quan et al. (US 6,180,133 B1) in view of Durr et al. (US 5,997,889) in view of Hill et al. (US 4,233,295) in view of McNulty et al. (US 2005/0048105 A1).

Applicant's arguments were fully considered, but not found persuasive.

Applicant states that the combination of references does not suggest all of the elements of Applicant's invention, and more particularly that Huard et al. does not teach or suggest a humectant including at least one of urea and ammonium lactate which is free of parabens (pp. 13-14, Remarks). Applicant further argues that Nagel et al. does not teach or suggest the elements missing from Huard because Nagel does not teach or suggest a composition containing a humectant such as urea and ammonium lactate which is free of parabens. Again, Applicant contends that they are not arguing the references separately, when it is apparent that they are arguing the references separately. It is reminded that the obviousness of the claims is held due to the combination of references taken as a whole and not due to one reference alone.

Applicant again argues that Nagel et al. does not provide motivation to remove parabens from cosmetics because Nagel et al. is specifically directed toward intravenous administration of parabens (pp. 14-15). Applicant states, "Nagel et al. does not teach or suggest patients with allergy or sensitivity to topical administration of parabens" (p. 15). However, Nagel et al. clearly state that reported paraben allergies to be on the rise, indicating that about 3% of the population had a topical paraben allergy (see p. 1594, column 1). Here, the paraben study was conducted by The North American Contact Dermatitis Group and therefore it is clear that the hypersensitivity occurred topically. Further, the reference also recites: "Recent and pending modifications of federal regulations requiring more complete and precise labeling of

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drugs, foods and **cosmetics** will facilitate **avoidance** of offending agents **by sensitized patients**" (p. 1595, last paragraph, emphasis added). Here, it is clear that it was *known in the art that patients were sensitized by parabens in cosmetics and thus had an allergy to topically applied parabens*. Additionally, although it is not explicitly stated in Nagel et al. to formulate cosmetics without parabens, Nagel et al.'s reference to the 'avoidance' of cosmetics with parabens is *clearly an implicit suggestion to the sensitized patient to use products which do not contain parabens*. Hence, the ordinary artisan would clearly see the advantage of formulating cosmetics such as humectants absent parabens because there was a need for such products according to the art at the time the invention was made.

Applicant states each reference of Huard et al., Nagel et al., Quan et al., Durr et al., Hill et al. and McNulty et al. and reiterates what the reference teaches and argues that "none of the cited reference taken in combination with one another teaches or suggests a composition that comprises urea or ammonium lactate and that is free of parabens or any composition that is free of parabens and thus states that the rejection should be withdrawn (p. 16, Remarks). Again, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant's arguments are not convincing. Save for the arguments against Nagel et al. whom Applicant states does not provide ample motivation to remove parabens from a Vaseline composition, Applicant continues to state that there is no motivation to combine well-known humectants and skin softening agents such as ammonium lactate and shea butter for example. However, it is clear that these agents were all known in the prior art for the same purpose; moisturizing the skin. In view of *In re Sussman* and *In re Kerkhoven*, it is deemed that the combination of these elements would have been *prima facie* obvious to one of ordinary skill in the cosmetic art. Claims directed toward 'consisting essentially of' are not rejected under 35 USC 102 because there is no explicit teaching of such; however, the compositions are still rendered obvious in view of the prior art since each component, such as sunflower oil and ammonium lactate for example, were *well known* in the art for treating the same ailments such as dryness of the skin. Thus, the ordinary artisan would have had a reasonable expectation that sunflower oil alone, or in combination with ammonium lactate alone (without any other ingredients) would have provided for additive effects with regard to skin moisturization.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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Claims 17-19 are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith  
Primary Examiner  
Art Unit 1655

June 21, 2007

A handwritten signature in black ink, appearing to read 'Patricia Leith', with a large, stylized loop at the end of the signature.